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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---|-----------------|----------------------|-------------------------|---------------------------------------|
| 10/789,729 | 02/27/2004 | G. Barrie Kitto | D6465 | 9702 |
| 52034 | 7590 12/01/2006 | | EXAMINER | |
| FULBRIGHT & JAWORSKI, L.L.P. 600 CONGRESS AVENUE SUITE 2400 | | | NAVARRO, ALBERT MARK | |
| | | | ART ŲNIT | PAPER NUMBER |
| AUSTIN, TX 78701 | | | 1645 | · · · · · · · · · · · · · · · · · · · |
| | | | DATE MAILED: 12/01/2006 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|--|---|---|--|--|--|--|
| | 10/789,729 | KITTO ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Mark Navarro | 1645 | | | | |
| The MAILING DATE of this communication app | pears on the cover sheet with the c | correspondence address | | | | |
| Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPL' WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period was a failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on 14 N | ovember 2006 | | | | | |
| ·- · · · · · · · · · · · · · · · · · · | Responsive to communication(s) filed on <u>14 November 2006</u> . This action is FINAL . 2b)⊠ This action is non-final. | | | | | |
| | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>2-12 and 23</u> is/are pending in the app | lication | | | | | |
| 4a) Of the above claim(s) <u>8</u> is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>2-7,9-12 and 23</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/o | r election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine | ÷ · | , | | | | |
| 10) The drawing(s) filed on is/are: a) acceptable | | Examiner | | | | |
| Applicant may not request that any objection to the | | | | | | |
| Replacement drawing sheet(s) including the correct | | | | | | |
| 11)☐ The oath or declaration is objected to by the Ex | | • | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12)☐ Acknowledgment is made of a claim for foreign | priority under 35 U.S.C. § 119(a) |)-(d) or (f). | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | , , , , , , , , , , , , , , , , , , , | , (=, 5. (-). | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3.☐ Copies of the certified copies of the prior | rity documents have been receive | ed in this National Stage | | | | |
| application from the International Bureau | ı (PCT Rule 17.2(a)). | | | | | |
| * See the attached detailed Office action for a list | of the certified copies not receive | ed. | | | | |
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| | | · | | | | |
| Attachment(s) | | | | | | |
| 1) U Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | (PTO-413) | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) | Paper No(s)/Mail Da 5) Notice of Informal P | | | | | |
| Paper No(s)/Mail Date <u>multiple</u> . | 6) 🔲 Other: | | | | | |

Application/Control Number: 10/789,729

Art Unit: 1645

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of SEQ ID NO: 2 in the reply filed on November 14, 2006 is acknowledged.

Claims 1 and 13-22 have been cancelled and new claim 23 has been added.

Consequently, claims 2-12 and 23 are pending in the instant application, of which claim 8, and claim 7 (SEQ ID NO: 1 and 3-9) have been withdrawn from further consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 1. Claims 2-6, 9-12 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Curtiss III et al.

The claims are directed to a method of inducing an immune response against an egg or sperm specific polypeptide in an animal comprising the step of allowing said animal to ingest a recombinant bacterial host useful as an immunocontraceptive vaccine, said bacterial host comprising a vector encoding an egg or sperm specific polypeptide.

Curtiss III et al (US Patent Number 5,656,488) disclose of bacterial hosts having a recombinant expression system which encodes at least one gamete-specific antigen. Curtiss III et al specifically disclose of Escherichia and Salmonella hosts, as well as sperm specific polypeptides of lactate dehydrogenase-C. (See claims). Additionally, Curtiss III et al disclose of incorporating heterologous proteins which have adjuvating properties, including cholera toxin, and orally administering the bacterial host. (See columns 12 and 15).

Accordingly, Curtiss III et al disclose each and every limitation of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 2-7, 9-12 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtiss III et al in view of Hogrefe et al.

The claims are directed to a method of inducing an immune response against an egg or sperm specific polypeptide in an animal comprising the step of allowing said animal to ingest a recombinant bacterial host useful as an immunocontraceptive

Art Unit: 1645

vaccine, said bacterial host comprising a vector encoding an egg or sperm specific polypeptide, wherein the specific polypeptide is SEQ ID NO: 2.

The teachings of Curtiss III are set forth above.

Curtiss III do not teach of a murine lactate dehydrogenase-C which is SEQ ID NO: 2.

Hogrefe et al (Journal of Biological Chemistry Vol. 262, No. 27, pp 13155-13162, 1987) teach of the structure of murine lactate dehydrogenase-C, and specifically a fragment, identified as peptide number 2, which is 100% identical to the instantly claimed SEQ ID NO: 2. (See page 13156). Hogrefe et al further set forth that this peptide is antigenic and induces a strong antibody response.

Given that 1) Curtiss III et al have taught of bacterial hosts comprising a vector encoding a lactate dehydrogenase-C polypeptide useful as an immunocontraceptive, and that 2) Hogrefe et al have taught of a specific peptide of murine lactate dehydrogenase-C which elicits a strong antibody response, it would have been prima facie obvious to have substituted the lactate dehydrogenase-C peptide (SEQ ID NO: 2) taught by Hogrefe et al in the bacterial host expressing lactate dehydrogenase-C as taught by Curtiss III et al. One would have been motivated to produce such a substitution based on the teachings of Hogrefe et al that lactate dehydrogenase-C peptide 2, elicited a strong antibody response, and the success of Curtiss showing that bacterial hosts expressing lactate dehydrogenase-C were successfully used as immunocontraceptives.

Application/Control Number: 10/789,729 Page 5

Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Mark Navarro Primary Examiner November 27, 2006